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(56) Documents cited
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(58) Field of search
UK CL (Edition L) A5R RFB
INT CL[5] A61B

(54) Fracture fixation device

(57) A fracture fixation device comprises a bone supporting plate component (10) and attachment means in the form of a plug arranged to be an interference fit within a pre-drilled hole in the bone without further damage to the bone. The plug (12) may be held in place by resilient barbs (32 Figure 2) or it can be expanded within the pre-drilled hole by an expanding member, such as pin (14). The pin and plug may be separate components. Alternatively, either the pin or the plug may be integral with the supporting plate. The device may be formed from a biologically degradable material such as a resorbable polymer or co-polymer, or from a composite material comprising a resorbable polymer and a particulate material. The particulate may be hydroxyapatite. A fracture fixation device formed from biologically degradable materials does not need to be removed from the body.

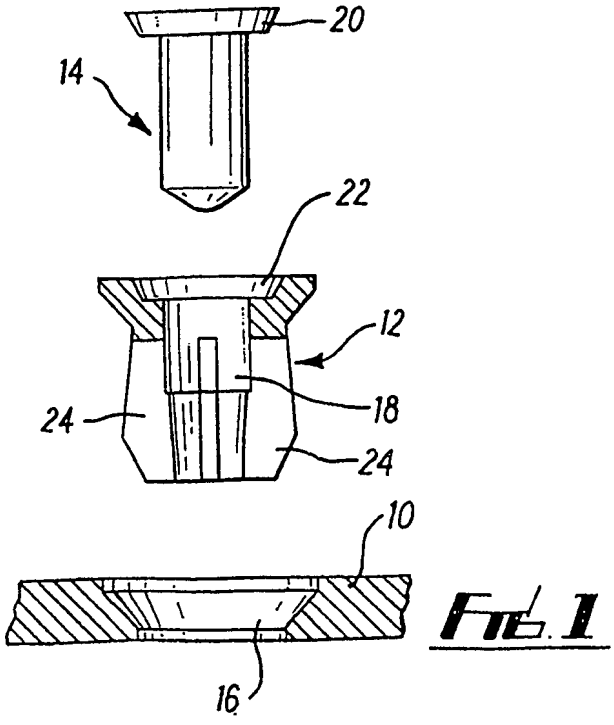

FIG. 1

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

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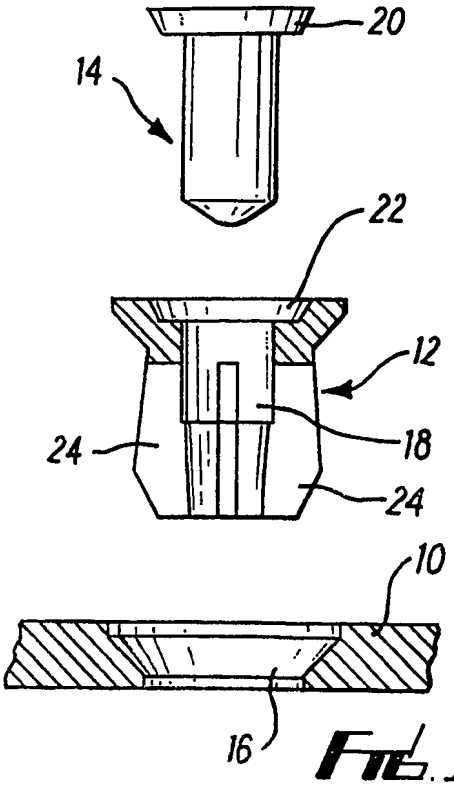


FIG. 1

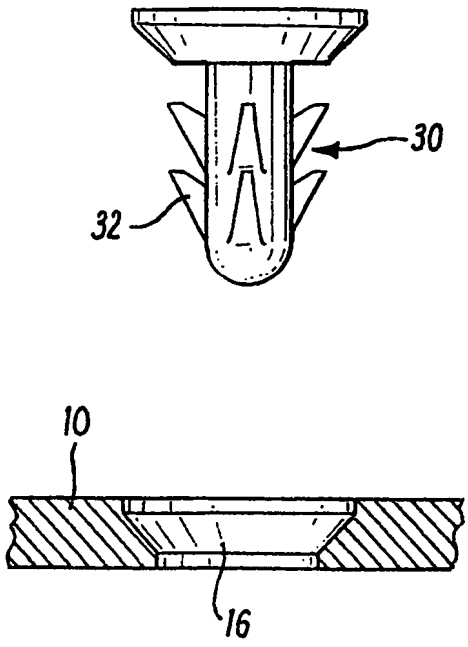
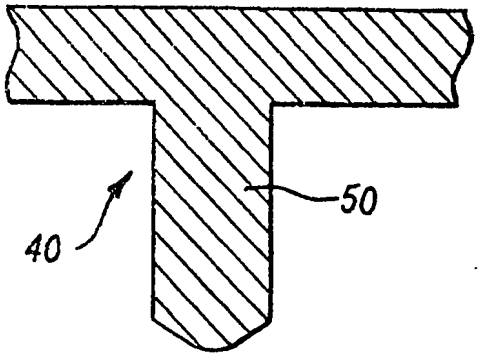
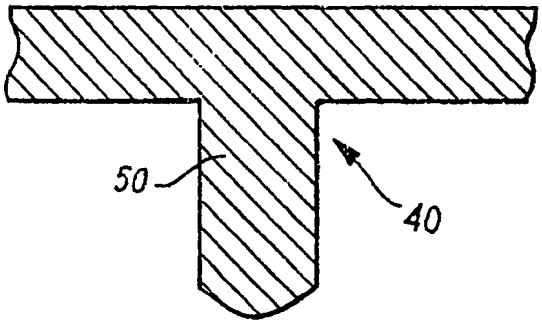


FIG. 2





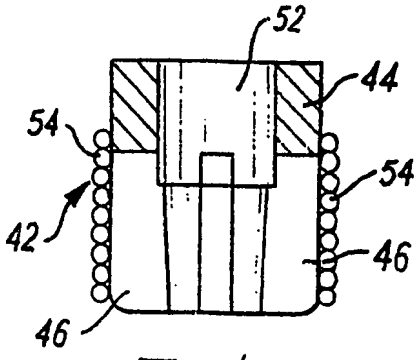


FIG. 3

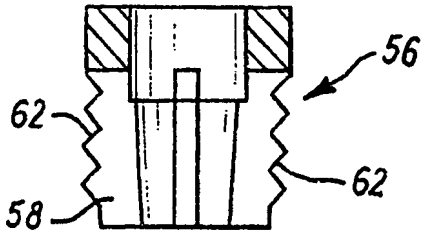


FIG. 4

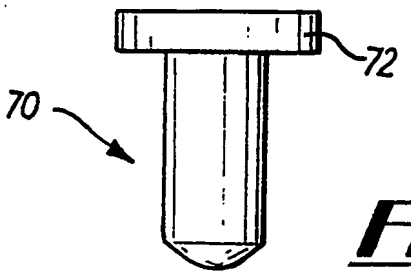
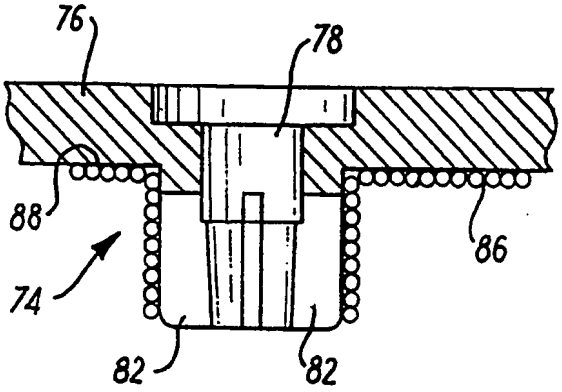


FIG. 5



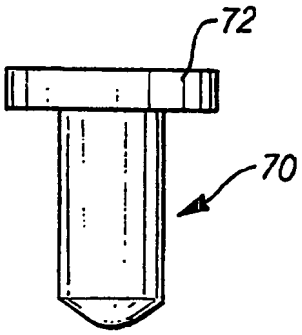
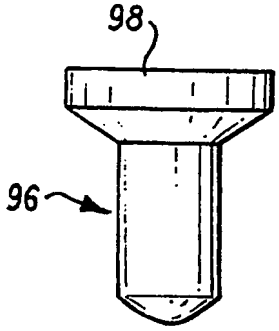
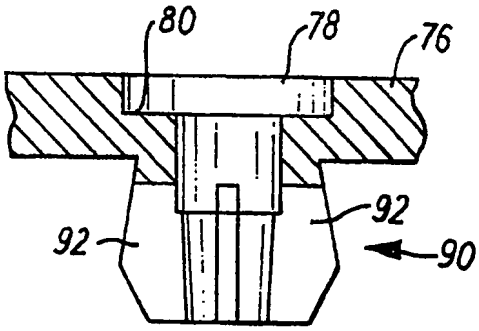


FIG. 6





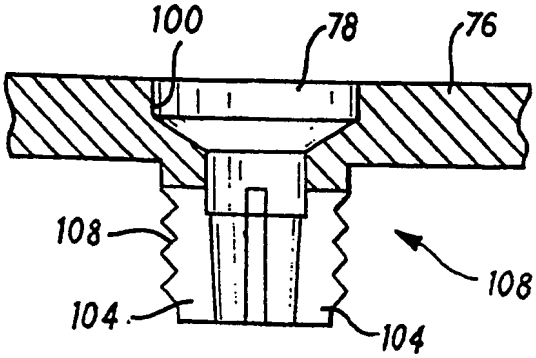
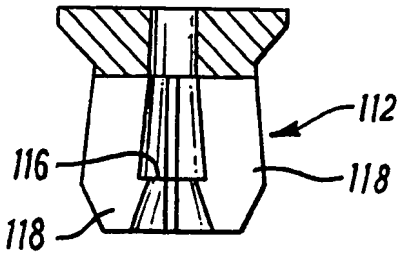
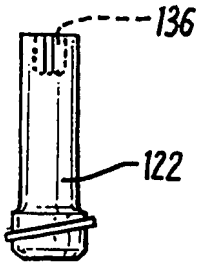


FIG. 7





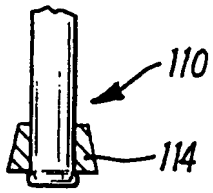


FIG. 8

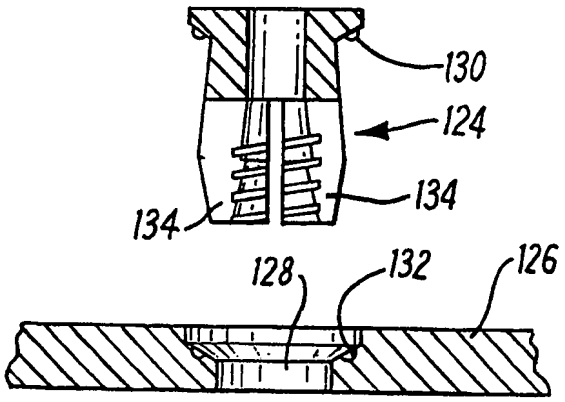
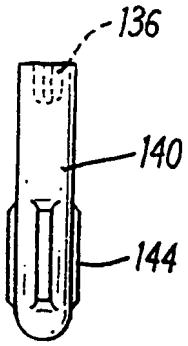


FIG. 9



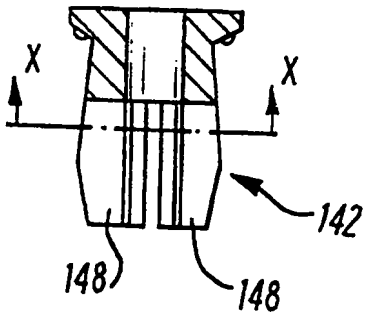


FIG. 10

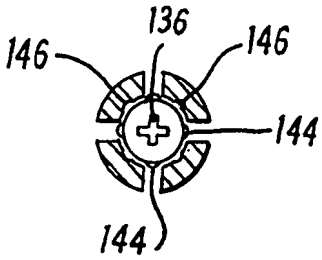


FIG. 11

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Fracture Fixation Device

The present invention relates to fracture fixation devices, and especially to internal devices suitable particularly but not exclusively for use in orthopaedic and maxillo-facial surgery in human and veterinary fields.

Fracture fixation devices are used to hold damaged or broken bones in alignment whilst healing takes place. Such devices may be either external or internal. Typical external devices comprise pins or screws which locate through the skin directly into the bone and are held in position by a rigid or semi-rigid bar external to the body. Traditionally, internal devices comprise a plate placed directly across the broken bone and held in place with pins or screws. In either case, the device is normally manufactured from stainless steel, cobalt chrome or titanium based metal. Once a satisfactory degree of healing has been achieved, a second invasive surgical procedure is often required to remove the device from the body. This naturally carries with it the risk of subsequent infection as well as subjecting the patient to a further operation.

Metal fixation devices also give rise to other

problems. The metals used have a considerably higher Young's modulus than natural bone and consequently have a stress shielding effect on the healing bone. This may delay the healing process, and can also result in the formation of weaker bone. In some cases, fractured bones may not unite. The presence of holes in the bones to locate the screws or pins results in areas of stress concentration which again can weaken the bone, leading to secondary fractures, particularly following removal of the plate and pins.

According to the invention there is provided a fracture fixation device comprising a support component and attachment means to hold the support component at a required location to restrict movement of a bone, the attachment means being locatable within a pre-drilled hole in the bone and having means for clamping the support component to the bone without further damage to the bone.

The attachment means preferably comprises a pin and plug arrangement, the plug having resiliently deformable jaws displacable by the pin to clamp the plug within the hole.

The pin and plug may be separate components, or the pin component may be integral with the support

component. Alternatively, the plug component may be integral with the support component.

Preferably the plug is adapted to prevent extraction thereof following clamping within the hole. The plug may be formed with serrations on an external surface thereof.

Alternatively, the attachment means may comprise a plug member having barbs on an external surface thereof.

Preferably the device is formed from biologically degradable material.

The degradable material may comprise a biologically degradable (resorbable) polymer or co-polymer. Alternatively, the material may be a composite material formed from a biologically degradable polymer or co-polymer together with either a particulate or a fibrous solid. Preferably the attachment means comprises a composite material. The support component may comprise a polymer or co-polymer or a composite material.

The polymer component preferably comprises at least one polymer or co-polymer of B-hydroxybutyrate (hydroxybutanoate), hydroxyvalerate (hydroxypentanoate), lactic acid (2-hydroxypropanoic acid) or glycolic acid (2-hydroxyethanoic acid).

The particulate solid is preferably biologically degradable (resorbable), and is further preferably a porcus material. In particular, the particulate solid may comprise hydroxyapatite, tri-calcium phosphate, calcium carbonate, calcium sulphate, magnesium oxide or bioactive glass. The fibrous material may be hydroxyapatite fibres or polymer fibres.

According to the invention there is further provided a fracture fixation device comprising a support component and attachment means to hold the support component at a required location to restrict movement of a bone, the device being formed from a biologically degradable material whereby the device does not require to be removed from the body after use.

Preferably the device comprises a degradable polymer or co-polymer or composite as defined hereinbefore.

The support component and/or the plug may be at least partially externally coated with the particulate material. More preferably, the coating comprises hydroxyapatite.

The invention will be further described with reference to the accompanying drawings in which:-

Fig. 1 shows a first fracture fixation device according to the invention;

Fig. 2 shows a second device;

Fig. 3 shows a device having a plate with integral pin;

Fig. 4 is similar to Fig. 3, but showing an alternative plug;

Fig. 5 shows a device having a plate with integral plug;

Fig. 6 is similar to Fig. 5, but shows an alternative plate and plug arrangement;

Fig. 7 shows a device with a yet further plate and plug arrangement;

Fig. 8 shows a further device according to the invention;

Figs. 9 and 10 show an alternative pin and plug arrangement; and

Fig. 11 is a section on line X-X of Fig. 10.

Fig. 1 shows a three part internal fracture fixation device suitable for use in orthopaedic and maxillofacial surgery. The device consists of a plate 10, a plug 12 and a pin 14. The plate 10 is formed from a biologically degradable (resorbable) polymer. The plug 12 and the pin 14 are each formed from a composite material comprising a biologically degradable polymer such as poly-B-hydroxybutyrate and a particulate material such as hydroxyapatite. Alternatively, the composite may comprise a biologically degradable polymer and a fibrous material. An aperture 16 is formed in

the plate 10 for the purpose of receiving the plug 12 as hereinafter described. The pin 14 is designed to be received within a through passage 18 in the plug 12. A head 20 at one end of the pin 14 locates within a corresponding recess 22 in one end of the plug 12. The plug 12 forms legs 24 at its other end.

In use of the device, a hole is first drilled in the bone (not shown). The diameter of the hole is similar to or slightly greater than that of the outside diameter of the plug 12. The plate 10 is positioned in contact with the bone, and the plug 12 is placed through the aperture 16 in the plate 10 into the drilled hole. The pin 14 is then pushed into the plug 12 forcing the legs 24 outwards slightly. This serves to provide a mechanical lock on the bone to fix the plate 10 in position.

Fig. 2 shows an alternative, two part arrangement having a plate 10 similar to that of Fig. 1, and a modified plug 30. The plate 10 is made from a resorbable polymer or a composite of a resorbable polymer and a resorbable particulate solid. The plug 30 is made from a composite of a resorbable polymer and hydroxyapatite. The plug 30 has a series of projecting barbs 32 located arounds its circumference. In use the plug 30 is pushed through the aperture 16 in the plate 10 and into a

pre-drilled hole in the bone. Once located in the bone, further movement of the plug is prevented by the barbs, which lock the device in position.

Figs. 3 and 4 illustrate an arrangement having an integral pin and plate component 40, which may be made of a resorbable polymer/hydroxyapatite composite material or a resorbable polymer/fibre composite material. The associated plug 42 shown in Fig. 3 has an annular upper portion 44 and depending legs 46. A hole is pre-drilled into the bone and the plug 42 is inserted therein. The pin part 50 of the component 40 is pushed into a through passage 52 in the plug 42 causing outward displacement of the legs 46 to lock the device into position. The outer surfaces of the legs 46 are provided with a coating 54 of particulate material, in this case hydroxyapatite. This results in increased friction between the legs 46 and the surrounding bone, providing good short term mechanical fixation. In the longer term, use of the hydroxyapatite may promote osteoconduction or bone regrowth.

Fig. 4 shows an integral pin/plate component 40 similar to that shown in Fig. 3 used in conjunction with a yet further design of plug 56. The plug 56 is generally similar in construction to the plug 42, except that legs 58 of the plug 56 have a series of serrations 62 on their outer sides in order to increase grip

between the plug 56 and the surrounding bone when the device is in use as described hereinbefore.

Figs. 5, 6 and 7 illustrate fracture fixation devices in which the plate is integral with the plug. Fig. 5 shows a device comprising a pin 70 having a head 72 at one end thereof. A second component 74 of the fixation device comprises a plate portion 76 having a through passage 78 one end of which is complementary in shape to the pin 70. Projecting legs 82 are formed on the component 74 adjacent the other end of the through passage 78. A coating 86 of hydroxyapatite is provided on the outer surfaces of the legs 82 and on the adjacent surface 88 of the plate 76. In use of the device a hole is drilled in the bone suitable to receive the projecting legs 82. The coating 86 ensures good contact between the bone and the surfaces of the component 74. The pin 70 is then inserted into the aperture 78. The legs 82 are thereby slightly outwardly displaced in order to lock the device in position.

The device of Fig. 6 uses a pin 70 similar to that shown in Fig. 5. The plate/plug component 90 is in many respects also similar to the structure 74 shown in Fig. 5, and accordingly corresponding parts are referred to by the reference numerals used in Fig. 5. The legs 92 of the component 90 shown in Fig. 6 are profiled to

ensure that the plug and plate cannot be removed easily once inserted into the bone.

In the device shown in Fig. 7, a pin 96 is formed with a head 98 at one end thereof. The plate/plug component 102 is similar to the corresponding components 74 and 90 shown in Figs. 5 and 6 respectively. The through aperture 78 in the plate 76 has a recess complementary to the pin head 98. The legs 104 are formed with a series of serrations 108 to anchor the device in the bone when the device is positioned for use as described hereinbefore.

The pin and plug devices of Figs. 1 to 7 are suitable for applications in which the bone is able to withstand the pressure of the pin being forced into the plug. In other applications, alternative forms of fixation device may be more appropriate. Fig. 8 illustrates a device in which a pin 110 is intended to be pulled through a plug 112 in an upwards direction as shown in the drawing by means of a tool not shown. The pin 110 may be formed of any material having sufficient tensile strength. A polymer composite bush 114 is located adjacent one end of pin 110. As the pin 110 is pulled through the plug 112, the bush 114 is drawn into the plug and retained therewithin by a step 116. Continued pulling on the pin allows removal of the pin whilst

leaving the bush 114 in position within the plug 112. The legs 118 are forced outwards to lock the plug in place in a pre-drilled hole in the bone. This is particularly suitable for use in regions where any pressure or twisting action to locate the device is unacceptable.

Fig. 9 shows a three component system in which a pin 122 is intended to be initially inserted loosely into a plug 124. The pin 122 and plug 124 are correspondingly screw threaded. The pin 122 has a suitable recess 136 at one end thereof to permit the application of a torque to the pin by means not shown. A hole is drilled in the bone and a plate 126 located adjacent to the hole. The plug 124 with the pin 122 loosely inserted therewithin is designed to be located within the hole through an aperture 128 in the plate 126. Locating studs 130 on the plug 124 are received within corresponding recesses 132 with aperture 128. Application of a torque action to the pin 122 causes legs 134 to be pushed outward, locking the pin and plug into the predrilled hole in the bone. The studs 130 prevent the plug 124 from moving whilst the pin 122 is positioned.

Figs. 10 and 11 show a further alternative pin 140 and plug 142 for use with the plate 126 of Fig. 9. The pin 140 is formed at its lower end with projecting lobes

144. The pin 140 is designed to be loosely inserted into the plug 142 before the latter is located within a hole in the bone through a plate as shown in Fig. 9. A torque is then applied to rotate the pin 140 causing the lobes 144 to locate in corresponding recesses 146 (Fig. 11) on the inside surfaces of legs 148 of the plug, displacing the legs outwardly and locking the plug into position in the bone.

Suitable resorbable polymer materials for use in the composite material of the pin and plug are polymers or co-polymers of B-hydroxybutyrate, hydroxyvalerate, lactic acid and glycolic acid. The particulate solid may be hydroxyapatite, tri-calcium phosphate, calcium carbonate, calcium sulphate, magnesium oxide or bio-active glass. The fibrous material may be hydroxyapatite fibres or polymer fibres. Composites of the abovementioned materials have a closer Youngs modulus to natural bone and when used in fracture fixation devices hence show a reduced stress shielding effect as compared to high modulus materials such as metals. The use of the described composite materials, particularly where the solid is hydroxyapatite, promotes bonding with natural bone and thus with time tends to seal the pre-drilled hole in the bone, eliminating potential weak points and lowering the probability of secondary fractures through the hole. The use of composite materials which are completely resorbable eliminates the need for further operations which are

often necessary when metal components are used. The complete fixation device will gradually be completely resorbed, thus in time allowing the healed natural bone to take over its normal function.

The composite materials described are easily worked by cutting, drilling, filing or moulding on the application of heat and/or pressure. The described fracture fixation devices may therefore be relatively easily and cheaply produced by known moulding processes, for example injection moulding. It is also relatively simple for the precise configuration of the device to be modified by the surgeon to suit the particular site of an operation.

It will be appreciated that modifications may be made to the fracture fixation device without departing from the scope of the invention. The exact configuration of the various components may differ from those described and shown. Coatings of particulate materials may be applied to surfaces of the device intended to come into contact in use with the bone, in order to facilitate mechanical fixation. Serrations and barbs may also be formed on outer surfaces of the plug for similar reasons. The materials employed for the manufacture of the fixation device may differ from those described.

Whilst endeavouring in the foregoing Specification to draw attention to those features of the invention believed to be of particular importance it should be understood that the Applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.